

REMARKS

Reconsideration is requested.

Claim 100 has been amended based on the amendments to claim 115. No new matter has been added. No new issues are raised by the amendments which would require further search and/or consideration as the subject matter of claim 115 has been previously considered. Moreover, claim 116 has been amended to be dependent from claim 114 and be similar in form to claim 113, but dependent on claim 114. Finally, claim 114 has been amended to specifically recite the deposited hybridomas for which deposit receipts and viability statements are attached as evidence of the deposits. The specification has been amended to include the information on the deposits. Both the original deposit receipts and viability statements in German text as well as in English translation of each is provided herewith. No new matter has been added. Entry of the above amendments is requested.

The Examiner is again requested to return an initialed copy of the previously filed PTO-1449 Form listing the PCT applications as filed on September 9, 2003 (i.e., PCT/US93/00907; PCT/IT92/00081; PCT/US92/07189; and PCT/US91/08272), which were originally listed in the PTO-1449 Form, filed October 10, 2001, copy of which the Examiner has returned with the Office Action of April 9, 2003 wherein these references have not been specifically initialed as having been considered. A similar request was made in the Remarks on page 10 of the Amendment filed September 9, 2003, and the Examiner has not responded to the same in the Office Action of December 17, 2003.

As noted earlier, these references were cited and considered in the parent application (Serial No. 08/612,973), as evidenced by the face of the corresponding U.S.

patent (U.S. Patent No. 6,150,134), which the Examiner has indicated has been considered and made of record in the present case. See, the initialed PTO-1449 Form considered April 1, 2003, by the present Examiner was returned with a copy of the Office Action of April 9, 2003 (Paper No. 12). Accordingly, the Examiner's comments with regard to the previously filed Information Disclosure Statement failing to comply with 37 CFR Section 1.98(a)(2), in paragraph 2 of Paper No. 12 is believed to be incorrect. Legible copy of the foreign patents are not required as the same were cited in the parent application. The Patent Office file should be complete in this regard and the applicants have no control over nor should they bear the burden of keeping the Patent Office copy of related files complete. See, MPEP Section 609. Moreover, the applicants should not bear the burden of additional cost and expenditure of the resources relating to providing further copies of references which presumably the Patent Office could obtain from their own resources. Out of a courtesy to the Examiner however the applicants have submitted on September 9, 2003, further copies of the indicated requested documents. Return of an initialed copy of the PTO-1449 Form indicating consideration of the WO documents cited on PTO-1449 Form filed October 10, 2001 pursuant to MPEP Section 609, is again respectfully requested. Return of a PTO 892 Form listing these references would suffice if more convenient for the Examiner. The Examiner's specific response to this request is again requested.

The Section 102 rejection of claims 100-104, 107-112 and 116-117 over U.S. Patent No. 5,308,750 (Mehta et al), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

The Examiner's interpretation of Mehta is, with all due respect, believed to be incorrect. Specifically, the applicants believe that one of ordinary skill in the art would draw the following conclusions from Mehta with regard to "the" antibody referred to by the Examiner on page 2 of the Office Action dated December 17, 2003 (Paper No. 17).

One of ordinary skill in the art would appreciate that Example 6 of Mehta describes a procedure for epitope mapping for the antibodies generated against the peptide of SEQ ID NO:6 (aa 643-683). Moreover, column 11, lines 38-44 of Mehta describes SEQ ID NO:6 of Mehta as the immunogen for the generation of monoclonal antibodies to HCV NS1. Further, Table 2 of Mehta (column 16) shows that monoclonal antibodies H13C113 and H23C163 have been identified and further tested. Table 2 of Mehta also shows that SEQ ID NO:3 (aa 643-663) and SEQ ID NO:4 (aa 666-683), have been separately used for epitope mapping of these antibodies. The clear conclusion which can be drawn by one of ordinary skill in the art is that monoclonal antibodies H13C113 and H23C163 of Mehta specifically reacted with SEQ ID NO:10 (aa 649-655) of the HCV genome. See, Figures 3 and 4 and column 4, lines 19-26 of Mehta. The applicants respectfully submit therefore that Mehta only discloses two antibodies and that the epitope for these antibodies consist of amino acids in the range 649-655. The Examiner's assertion that Mehta teaches an antibody which binds to the region of amino acids 666-683 or 671-691 is believed to be an incorrect interpretation and further explanation and clarification is requested in the event the Examiner maintains the rejection.

As the product claims are submitted to be patentable over Mehta, the dependent claims are similarly submitted to be patentable over Mehta. See, the Examiner's comments in paragraph 5 and paragraph 6 on page 3 of Paper No. 17.

The Examiner's comments in paragraph 7 on page 3 of Paper No. 17 are noted however as Mehta is believed to clearly identify the amino acid region, as explained above, the Patent Office is not believed to require facilities to perform physical comparisons, as suggested in paragraph 7 on page 3 of Paper No. 17.

The claims are submitted to be patentable over Mehta and withdrawal of the Section 102 rejection is requested.

The Section 103 rejection of claims 100-113, 115 and 117-118 over De Leys (WO93/183542) and Matsuura (Journal of Virology 1992, 66(3), pp 1425-1431), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Initially, the applicants note the Examiner's reference to "Rosa et al" in paragraph 12 of Paper No. 17 is not understood. There has been no article of "Rosa et al" made of record by the Examiner or by the applicants. Moreover, the statement of the rejection does not include reference to an article by or patent of "Rosa et al". A new, non-final, Office Action is requested if any further reference is being relied on by the Examiner, such as the previously referred to and unidentified "Rosa et al", with a clear statement of any rejection based on the same. Clarification is requested with regard to the apparent document referred to by the Examiner as "Rosa et al".

As for the references cited in paragraph 10 of Paper No. 17 as a basis for the rejection, the applicants note the Examiner's specific reliance on SEQ ID NO:72 of the


present application and the Examiner's assertion that the same is described in De Leys. See, paragraph 12 of Paper No. 17. The above amendments have been made to advance prosecution and specifically claim 115 and claim 100, as well as claims dependent therefrom, do not include a recitation of the identified SEQ ID NO:72. Accordingly, while not believed to be required, the claims, as amended, are submitted to be patentable over the cited combination of art. Entry of the above and withdrawal of the Section 103 rejection are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

The Examiner is requested to contact the undersigned if anything further is required in this regard.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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BUDAPESTER VERTRAG ÜBER DIE INTERNATIONALE
ANERKENNUNG DER HINTERLEGUNG VON MIKROORGANISMEN
FÜR DIE ZWECKE VON PATENTVERFAHREN

DSMZ

Deutsche Sammlung von
Mikroorganismen und
Zellkulturen GmbH

INTERNATIONALES FORMBLATT


Innogenetics N.N.

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9052 Gent-Zwijnaarde

Belgium

EMPFANGSBESTÄTIGUNG BEI ERSTHINTERLEGUNG,
ausgestellt gemäß Regel 7.1 von der unten angegebenen
INTERNATIONALEN HINTERLEGUNGSSTELLE

I. KENNZEICHNUNG DES MIKROORGANISMUS	
Vom HINTERLEGER zugeteiltes Bezugszeichen: 16A6E7	Von der INTERNATIONALEN HINTERLEGUNGSSTELLE zugeteilte EINGANGSNUMMER: DSM ACC2616
II. WISSENSCHAFTLICHE BESCHREIBUNG UND/ODER VORGESCHLAGENE TAXONOMISCHE BEZEICHNUNG	
Mit dem unter I. bezeichneten Mikroorganismus wurde <input checked="" type="checkbox"/> (X) eine wissenschaftliche Beschreibung <input type="checkbox"/> () eine vorgeschlagene taxonomische Bezeichnung eingereicht. (Zutreffendes ankreuzen).	
III. EINGANG UND ANNAHME	
Diese internationale Hinterlegungsstelle nimmt den unter I bezeichneten Mikroorganismus an, der bei ihr am 2003-09-10 (Datum der Erst- hinterlegung) ¹ eingegangen ist.	
IV. EINGANG DES ANTRAGS AUF UMWANDLUNG	
Der unter I bezeichnete Mikroorganismus ist bei dieser Internationalen Hinterlegungsstelle am eingegangen (Datum der Erst- hinterlegung) und ein Antrag auf Umwandlung dieser Ersthinterlegung in eine Hinterlegung gemäß Budapester Vertrag ist am eingegangen (Datum des Eingangs des Antrags auf Umwandlung).	
V. INTERNATIONALE HINTERLEGUNGSSTELLE	
Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Anschrift: Mascheroder Weg 1b D-38124 Braunschweig	Unterschrift(en) der zur Vertretung der internationalen Hinterlegungsstelle befugten Person(en) oder des (der) von ihr ermächtigten Bediensteten:  Datum: 2003-09-18

¹ Falls Regel 6.4 Buchstabe d zutrifft, ist dies der Zeitpunkt, zu dem der Status einer internationalen Hinterlegungsstelle erworben worden ist.

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

DSMZ

Deutsche Sammlung von
Mikroorganismen und
Zellkulturen GmbH



INTERNATIONAL FORM

Innogenetics N.N.

Industriepark Zwijnaarde 7/4

9052 Gent-Zwijnaarde

Belgium

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: 16A6E7	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: DSM ACC2616
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I. above was accompanied by: (X) a scientific description () a proposed taxonomic designation (Mark with a cross where applicable).	
III. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on 2003-09-10 (Date of the original deposit) ¹ .	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depositary Authority on (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Mascheroder Weg 1b D-38124 Braunschweig	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): <i>V. Weis</i> Date: 2003-09-18

¹ Where Rule 6.4 (d) applies, such date is the date on which the status of international depositary authority was acquired.



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LEBENSFÄHIGKEITSBESCHEINIGUNG
ausgestellt gemäß Regel 10.2 von der unten angegebenen
INTERNATIONALEN HINTERLEGUNGSSTELLE

I. HINTERLEGER		II. KENNZEICHNUNG DES MIKROORGANISMUS	
Name: Innogenetics N.N. Industriepark Zwijnaarde 7/4 Anschrift: 9052 Gent-Zwijnaarde Belgium		Von der INTERNATIONALEN HINTERLEGUNGSSTELLE zugeteilte EINGANGSNUMMER: DSM ACC2616 Datum der Hinterlegung oder Weiterleitung ¹ : 2003-09-10	
III. LEBENSFÄHIGKEITSBESCHEINIGUNG			
Die Lebensfähigkeit des unter II genannten Mikroorganismus ist am 2003-09-10 ² geprüft worden. Zu diesem Zeitpunkt war der Mikroorganismus (X) ³ lebensfähig () ³ nicht mehr lebensfähig			
IV. BEDINGUNGEN, UNTER DENEN DIE LEBENSFÄHIGKEITSPRÜFUNG DURCHGEFÜHRT WORDEN IST⁴			
V. INTERNATIONALE HINTERLEGUNGSSTELLE			
Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Anschrift: Mascheroder Weg 1b D-38124 Braunschweig		Unterschrift(en) der zur Vertretung der internationalen Hinterlegungsstelle befugten Person(en) oder des (der) von ihr ermächtigten Bediensteten: Datum: 2003-09-18	

¹ Angabe des Datums der Ersthinterlegung. Wenn eine erneute Hinterlegung oder eine Weiterleitung vorgenommen worden ist, Angabe des Datums der jeweils letzten erneuten Hinterlegung oder Weiterleitung.
² In den in Regel 10.2 Buchstabe a Ziffer ii und iii vorgesehenen Fällen Angabe der letzten Lebensfähigkeitsprüfung.
³ Zutreffendes ankreuzen.
⁴ Ausfüllen, wenn die Angaben beantragt worden sind und wenn die Ergebnisse der Prüfung negativ waren.

BUDAPEST TREATY ON THE INTERNATIONAL
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FOR THE PURPOSES OF PATENT PROCEDURE



INTERNATIONAL FORM

Innogenetics N.N.
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9052 Gent-Zwijnaarde
Belgium

VIABILITY STATEMENT
issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: Innogenetics N.N. Industriepark Zwijnaarde 7/4</p> <p>Address: 9052 Gent-Zwijnaarde Belgium</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:</p> <p>DSM ACC2616</p> <p>Date of the deposit or the transfer¹:</p> <p>2003-09-10</p>
III. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 2003-09-10².</p> <p>On that date, the said microorganism was</p> <p>(<input checked="" type="checkbox"/>)³ viable</p> <p>(<input type="checkbox"/>)³ no longer viable</p>	
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED ⁴	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH</p> <p>Address: Mascheroder Weg 1b D-38124 Braunschweig</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p><i>V. Wechs</i></p> <p>Date: 2003-09-18</p>

- ¹ Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- ² In the cases referred to in Rule 10.2(a) (ii) and (iii), refer to the most recent viability test.
- ³ Mark with a cross the applicable box.
- ⁴ Fill in if the information has been requested and if the results of the test were negative.

BUDAPESTER VERTRAG ÜBER DIE INTERNATIONALE
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FÜR DIE ZWECKE VON PATENTVERFAHREN



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EMPFANGSBESTÄTIGUNG BEI ERSTHINTERLEGUNG,
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INTERNATIONALEN HINTERLEGUNGSSTELLE

I. KENNZEICHNUNG DES MIKROORGANISMUS	
Vom HINTERLEGER zugeteiltes Bezugszeichen: 12D11F1	Von der INTERNATIONALEN HINTERLEGUNGSSTELLE zugeteilte EINGANGSNUMMER: DSM ACC2615
II. WISSENSCHAFTLICHE BESCHREIBUNG UND/ODER VORGESCHLAGENE TAXONOMISCHE BEZEICHNUNG	
<p>Mit dem unter I. bezeichneten Mikroorganismus wurde</p> <p>(X) eine wissenschaftliche Beschreibung () eine vorgeschlagene taxonomische Bezeichnung</p> <p>eingereicht. (Zutreffendes ankreuzen).</p>	
III. EINGANG UND ANNAHME	
Diese internationale Hinterlegungsstelle nimmt den unter I bezeichneten Mikroorganismus an, der bei ihr am 2003-09-10 (Datum der Erst-hinterlegung) ¹ eingegangen ist.	
IV. EINGANG DES ANTRAGS AUF UMWANDLUNG	
Der unter I bezeichnete Mikroorganismus ist bei dieser Internationalen Hinterlegungsstelle am _____ eingegangen (Datum der Erst-hinterlegung) und ein Antrag auf Umwandlung dieser Ersthinterlegung in eine Hinterlegung gemäß Budapest Vertrag ist am _____ eingegangen (Datum des Eingangs des Antrags auf Umwandlung).	
V. INTERNATIONALE HINTERLEGUNGSSTELLE	
<p>Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH</p> <p>Anschrift: Mascheroder Weg 1b D-38124 Braunschweig</p>	<p>Unterschrift(en) der zur Vertretung der internationalen Hinterlegungsstelle befugten Person(en) oder des (der) von ihr ermächtigten Bediensteten:</p> <p><i>V. Weh</i></p> <p>Datum: 2003-09-18</p>

¹ Falls Regel 6.4 Buchstabe d zutrifft, ist dies der Zeitpunkt, zu dem der Status einer internationalen Hinterlegungsstelle erworben worden ist.

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Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Mascheroder Weg 1b D-38124 Braunschweig	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 2003-09-18

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I. HINTERLEGER		II. KENNZEICHNUNG DES MIKROORGANISMUS	
Name: Innogenetics N.N. Industriepark Zwijnaarde 7/4 Anschrift: 9052 Gent-Zwijnaarde Belgium		Von der INTERNATIONALEN HINTERLEGUNGSSTELLE zugeteilte EINGANGSNUMMER: DSM ACC2615 Datum der Hinterlegung oder Weiterleitung ¹ : 2003-09-10	
III. LEBENSFÄHIGKEITSBESCHEINIGUNG			
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IV. BEDINGUNGEN, UNTER DENEN DIE LEBENSFÄHIGKEITSPRÜFUNG DURCHGEFÜHRT WORDEN IST⁴			
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³ Zutreffendes ankreuzen.
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Name: Innogenetics N.N. Industriepark Zwijnaarde 7/4 Address: 9052 Gent-Zwijnaarde Belgium		Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: DSM ACC2615 Date of the deposit or the transfer ¹ : 2003-09-10	
III. VIABILITY STATEMENT			
The viability of the microorganism identified under II above was tested on 2003-09-10 ² . On that date, the said microorganism was (X) ³ viable () ³ no longer viable			
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED ⁴			
V. INTERNATIONAL DEPOSITARY AUTHORITY			
Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Mascheroder Weg 1b D-38124 Braunschweig		Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 2003-09-18	

- ¹ Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
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³ Mark with a cross the applicable box.
⁴ Fill in if the information has been requested and if the results of the test were negative.